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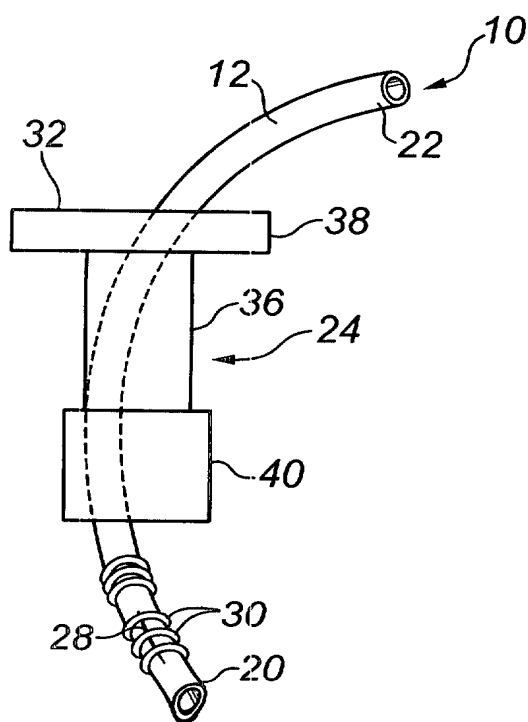
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(54) Title: A SHUNT AND METHOD TREATMENT OF GLAUCOMA



(57) Abstract: This invention provides a shunt for implantation between the anterior chamber of the eye and the epithelial-lined space through the frontal sinus bone of a patient for the treatment of glaucoma. The shunt includes a tube having a length sufficient to span the distance between the anterior chamber of the eye and the epithelial-lined space of the patient, the tube having an open anterior chamber end and a closed epithelial-lined space end, and a seal device associated with the tube between the anterior chamber and epithelial-lined space ends, for sealing a hole in the frontal sinus bone, and for anchoring the tube against movement from the frontal sinus bone. The shunt also includes a fluid pressure openable valve in the tube, located at or near the epithelial-lined space sinus end, allowing for controlled flow of aqueous humor through the tube when implanted. The invention also extends to a method of treating glaucoma in a patient by surgically implanting the shunt between the anterior chamber of the eye and the frontal sinus.



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A SHUNT AND METHOD TREATMENT OF GLAUCOMA

FIELD OF INVENTION

The present invention relates to a method and device for controlling aqueous humor flow from the anterior chamber of the eye in the treatment of glaucoma.

BACKGROUND OF THE INVENTION

Glaucoma is a medical condition in which the intraocular pressure of the eye increases. The anterior chamber, the cavity located between the cornea and lens, is filled with a fluid called aqueous humor. The aqueous humor drains from the anterior chamber to the venous system through the canals of Schlemm and is replaced continuously by secretions from the ciliary body. Glaucoma occurs when aqueous humor does not drain properly from the anterior chamber, causing an increase in intraocular pressure, closure of surrounding blood vessels, and damage to the retina and optic nerve. This condition, left untreated, can be very painful and lead to blindness. It is estimated that 65 million people world-wide suffer from this condition (Glaucoma Research Foundation, 2002). Animals can also be affected by this condition. It is estimated there are 65 million dogs in North America, of which approximately 1.3 million will develop glaucoma.

Closed-angle glaucoma occurs when the iris becomes misshapen and blocks the canals of Schlemm. The underlying cause of open-angle glaucoma is a blockage within the canals. About 3 million people in the United States are afflicted with open-angle glaucoma (Glaucoma Research Foundation, 2002). Secondary glaucoma, either open- or closed-angle, can be caused by injury, abnormal structures, inflammation, tumours, certain drugs, or diseases (Moffett et al, 1993).

Current treatments consist of medications, laser surgery and implantable drainage devices (Glaucoma Research Foundation, 2002). Medications, often in the form of eye drops, work to decrease intraocular fluid production, increase fluid drainage, or both. These medications are associated with side effects, including burning sensations in the eye, headaches, cardiac fluctuations and blurred vision. The administration of medications for the treatment of animals is difficult and ineffective. Laser surgery is used to open the fluid

draining channels or correct structures in the eye. Multiple surgeries are often required, and medication is normally still used to help control intraocular pressure post-surgery. There is also the risk of allowing too much fluid to drain from the anterior chamber, resulting in hypotony and flattening of the eye.

Implants have also been used in the treatment of glaucoma. These implants drain aqueous humor from the anterior chamber into mesenchymal or subconjunctival tissues surrounding the eye. The aqueous humor of eyes afflicted with glaucoma has a relatively high concentration of cytokines. Cytokines are proteins that mediate the generation of an immune response. Implants that drain aqueous humor into tissues surrounding the eye induce scarring in such tissues, which scarring ultimately inhibits absorption of fluid from the shunt. Consequently glaucoma recrudesces and visual impairment redevelops.

Current drainage implants are classified as either restrictive or non-restrictive flow devices (Gal, 1999). Non-restrictive flow devices, such as the Molteno drainage implant, rely on the formation of fibrous tissue to slow the drainage of fluid from the eye. These implants require at least two invasive surgical procedures. The initial surgery is required to implant the device. Fibrous tissue generally takes several weeks to form, making it necessary to clamp or tie the device to limit fluid drainage and prevent hypotony. A second surgery is required to unclamp or untie the device once fibrosis has occurred. Restrictive flow devices, such as the Krupin Eye Disk, are designed with components that respond to fluid pressure, see for example U.S. Patent 5,454,796, issued October 3, 1995 to Krupin, and U.S. Design Patent Des. 356,867 issued March 28, 1995 to Krupin. When pressure in the drainage tube exceeds a certain limit, the component, or valve, will open and allow fluid to drain. Several problems have occurred with these devices. First, it is difficult to calibrate the valve to maintain an optimal intraocular pressure, and often leads to hypotony. Second, the formation of fibrous tissue can occlude the valve and render the drainage device useless. A similar restrictive flow device is disclosed in U.S. Patents 6,142,969 and 6,007,510, issued to Nigam.

The frontal sinus 16 is an epithelium-lined cavity which is not affected by cytokines. Studies by Cullen et al., with a shunt implanted in dogs between the anterior chamber and the frontal sinus showed no evidence of bacterial movement from the frontal sinus 16 to the eye through this device (see Cullen et al, 1998).

Although somewhat successful in less severe cases, the prior art implant devices, while successful in the short term, are not effective for long-term management of glaucoma

due to occurrence of hypotony or more difficult forms of glaucoma. More effective treatment regimes are needed.

SUMMARY OF INVENTION

To overcome the difficulties induced by fibrosis blocking the valve or drainage tube and the scarring invoked by the cytokine response, the inventors have developed a shunt device and method of treatment for glaucoma that diverts aqueous humor from the anterior chamber to an epithelial-lined space. While the method and device have been successfully demonstrated with dogs, in which the shunt was implanted between the anterior chamber of the eye and the frontal sinus, the invention has application for the treatment of glaucoma in all species of animals, including humans, and to other epithelial-lined spaces besides the frontal sinus.

The term "epithelial-lined space", as used herein and in the claims includes epithelial and epithelial-lined spaces, including the frontal sinus, maxillary sinus, nasal sinus, other respiratory sinuses or spaces, subdural space, and meningeal cavity.

Broadly, the invention provides a shunt for implantation between the anterior chamber of the eye and the epithelial-lined space through the frontal sinus bone of a patient for the treatment of glaucoma. The shunt includes a tube having a length sufficient to span the distance between the anterior chamber of the eye and the epithelial-lined space of the patient, the tube having an open anterior chamber end and a closed epithelial-lined space end, and a seal device associated with the tube between the anterior chamber and epithelial-lined space ends, for sealing a hole in the frontal sinus bone, and for anchoring the tube against movement from the frontal sinus bone. The shunt also includes a fluid pressure openable valve in the tube, located at or near the epithelial-lined space sinus end, allowing for controlled flow of aqueous humor through the tube when implanted.

The invention also broadly provides a method of treating glaucoma in a patient, comprising (a) forming a hole from the exterior into the epithelial-lined space, for example in the frontal sinus bone, of the patient; (b) surgically implanting through the hole, between the anterior chamber and the epithelial-lined space, a shunt having a fluid pressure openable valve; and (c) draining aqueous humor from the anterior chamber through the shunt to the epithelial-lined space. The shunt preferably includes a tube having an open anterior chamber

end and a closed epithelial-lined space end, and wherein the valve is located at the frontal sinus end, allowing for controlled flow of aqueous humor through the tube when implanted.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 illustrates the shunt of the present invention implanted in a dog, with portions of the eye being cut away to illustrate placement of the shunt between the anterior chamber and the frontal sinus;

Figure 2 is a sectional view of the shunt implanted in the eye, better illustrating the anterior chamber placement.

Figure 3 is a sectional view of the shunt threaded through the anchoring sealing device.

Figure 4 is a sectional view of the shunt showing the anchoring sealing device in place in the hole in the frontal sinus bone.

Figure 5 is a partial perspective view of the shunt showing the slit valve and the ligatures used to adjust and control flow of aqueous humor through the valve.

Figure 6 is a schematic side sectional view of a second embodiment of a shunt of the present invention, illustrating a drainage reservoir housing for alternate valve devices.

Figure 7 is an a schematic side sectional view of a third embodiment of a shunt of the present invention, illustrating a drainage reservoir for housing alternate valve devices, which drainage reservoir also functions as the sealing device.

Figure 8 is a perspective view, partially cut-away, showing a tapered nipple plug type valve within the reservoir chamber of either Figures 7 and 8.

Figure 9 is a perspective view, partially cut-away, showing the tapered nipple plug valve of Figure 8 in the open position.

Figure 10 is a perspective view of the taper nipple plug valve unit of Figures 8 and 9.

BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENTS

The shunt of the present invention, shown generally at 10 in the Figures is shown as designed for implantation between the anterior chamber and the frontal sinus, however, the shunt has application for implantation to other epithelial-lined spaces, including the maxillary

sinus, nasal sinus, other respiratory sinuses or spaces, subdural space, and meningeal cavity.

The details of a first embodiment of the shunt 10 are best shown in Figures 3 - 5, while the placement of the shunt 10 in a dog is shown in Figures 1 and 2. The shunt 10 consists of a tube 12, made of a biocompatible material such as silicone. The length of the tube required is dependent on the species, but is of sufficient length to reach the distance between the anterior chamber 14 and the frontal sinus 16, through the frontal sinus bone 18, of the given animal species. The tube 12 thus has a frontal sinus end 20 and an anterior chamber end 22. The tube 12 is threaded through a sutureless sealing device 24, which seals around the hole 25 in the frontal sinus bone 18. The sealing device 24 is located close to the frontal sinus end 20 of the tube 12. This acts to hold the tube 12 in place as well as prevents it from kinking. A valve device 26 is provided at or near the frontal sinus end 20 of the tube 12 (i.e., when implanted the valve is on the sinus side of the frontal sinus bone). The sealing device 24 also functions to prevent serum and clots from exuding from the exposed bone 18 and from subcutaneous tissues within the frontal sinus and into the valve device 26. In Figures 1 and 3, the valve device 26 is shown to be of a slit valve type, formed by constructing a slit 28 in the frontal sinus end 20 of the tube 12 approximately parallel to the longitudinal axis of the tube 12. This frontal sinus end 20 is inserted into the frontal sinus 16 and held in place with the sealing component 24, which straddles the frontal sinus bone 18 and anchors the tube against movement in either direction. The tube 12 is then tunnelled subcutaneously towards the eye and into the anterior chamber 14. Surgical implantation of the shunt 10 is more fully explained below.

The shunt will generally have a length ranging from 30 to 150 mm, and may be trimmed to length during surgery. However, the shunt can be made to fit any species of animal (including humans) by trimming any excess length from the anterior chamber end 22. The shunt is generally formed from flexible, biocompatible materials such as silicone, glass, medical grade acrylics, plastic, or metal manufactured parts, with silicone or any similar biocompatible, flexible material being most preferred. One advantage of the present invention is that the tube 12 of the shunt 10 can be formed from tubing having internal and external diameters that can be varied according to the patient species together with the surgeon's preference and/or the surgeon's skill. The dimensions are affected by the space available in a particular patient's eye between the cornea and the lens. The tube 12 should be sized so as to be fitted into such space in such a fashion that the anterior chamber end 22 does

not contact the iris, lens or cornea. While not being limiting, exemplary dimensions for the shunt of the present invention for implantation in dogs, taking into account the ordinary skill of a surgeon, are as follows. For the tube portion 12, flexible tubing (such as silastic tubing) ranging from 0.25 to 0.64 mm inner diameters and 0.6 to 0.14 mm outer diameters with a wall thickness from 0.2 to 0.64 mm are optimal.

The method and shunt 10 of the present invention allows for the control of aqueous humor flow from the valve device 26 by means of a simple adjustment procedure, explained more fully below. A major constraint of prior art glaucoma shunts, the control of intraocular pressure via fluid flow from valves, is addressed with the present invention in that the flow of aqueous humor is controlled by using an adjustable valve, or by associating a flow control device with a valve. As best shown in Figure 5, flow adjustment through the slit 28 is provided by means of one or more ligature devices 30. The ligature devices 30 may be formed from O-rings, D-rings, C-clamps, sutures, or circumferential sutures formed of a biocompatible material, which are placed or tied around the tube 12 over and/or adjacent the slit 28. These ligature devices 30 tighten the slit 28, allowing less fluid to escape from the tube 12 and drain from the anterior chamber 14. The addition or removal of these ligature devices 30 to control flow can be made by a simple skin incision above the frontal sinus 16, which also allows for easy removal of the shunt 10 (more fully described below). Hydrostatic pressures of aqueous humor of glaucoma-affected patients can vary among species and idiosyncratically among patients. Also, rates of aqueous fluid of different species vary significantly. The easy adjustment of the valve device 26 allows this shunt 10 to be used in the treatment of various species, as well as each individual within a species.

The slit 28 will generally be about 0.5 to 2.0 mm long, and oriented approximately parallel to the longitudinal axis of the tube 12. The slit 28 is preferably perpendicular to the tangent of the tube wall. Variability in the length of the slit, the number of slits, the number of ligature devices and the positioning of ligature devices in relation to the slit provides flexibility sufficient to permit adjustment for use with various species, as well as various hydrostatic pressures of aqueous humor.

As shown in Figure 5, the ligature devices 30 around the tube 12, are mounted circumferentially around the longitudinal axis of the slit 28 and snug enough to slightly indent the tube 12 without disturbing the orientation of the slit. The ligature devices 30 are formed of a biocompatible material, with metal C-shaped clamps, and plastic, silicone, or

rubber round O-rings, being most preferred. These preferred ligature devices are less prone to surgeon error than sutures in that they can be sized such that they do not excessively compress the valve walls and can be pre-placed at one or both ends of the slit 28. During surgical placement, these ligature devices 30 are slidably moved into variable positions along the length of the slit 28, and the intraocular pressure (fluid pressure indicative of glaucoma operative to open valve) is measured to ensure a desired intraocular pressure will open the valve device 26. Multiple ligature devices, up to 3/mm, have been found to provide flexibility that allows the surgeon to finely adjust valve tension and aqueous flow rates through the valve device 26.

The sealing device 24 can take a variety of forms, such as a widened portion (not shown) of the tube 12, a widened reservoir plug as shown in Figure 7, or a spool-shaped plug type seal as shown in Figures 3 and 4. It is functional to seal the shunt 10 against the hole 25 in the frontal sinus bone 18, and to anchor the shunt against movement relative to the bone 18 once implanted. The sealing device also bends the tube 12 through an angle sufficient to ensure that the valve device 26, when the shunt 10 is implanted, is wholly within the frontal sinus and maintained in the space (not abutting the frontal sinus epithelium. For most species of patients, an bending angle of 80 to 100° is desired, so as to maintain the most desired ingress and egress angle of the shunt between the frontal sinus 16 and the anterior chamber 14. This best positions the shunt 10 and avoids narrowing of the lumen of the tube 12 or kinking of the tube 12. In one embodiment designed for dogs, an angle of about 90° was used.

The sealing device is most preferably a molded, spool-shaped (grommet-like) plug 32, attached to the tube 12 and having an central bore 34 sized to fit snugly around the tube 12. The plug may be manufactured by carving a wax or wooden mold, positioning the tube 12 in the mold at the desired ingress and egress angles, flooding the mold with liquid silicone, allowing it to set and removing the plug from the mold. The plug 32 has a central portion 36 joined to and an upper flange or lip (anterior chamber facing) 38 and a lower flange or lip (frontal sinus facing) 40. The flanges 38, 40 have a widened diameter relative to the diameter of the central portion 36. Biocompatible materials for the plug are silicone (a preferred embodiment) and rubber, plastic, glass, or metal components. At least the lower flange 40, which is frontal sinus facing, is made of a viscoelastic material such as silicone, to enable it to be compressed and forced through the hole 25 in the sinus bone 18. As mentioned above,

the plug 32 bends the tube 12 though about an 80 to 100 ° angle.

The shunt 10 should enter the anterior chamber 10 - 25 degrees anterior to the limbal plane to avoid contact with the iris, crystalline lens, or corneal endothelium. The trephine hole 25 of the frontal sinus 16 is best situated approximately perpendicular to the frontal bone 18. The tube 12 should enter and leave the at plug 32 at about 90 ° (i.e., bend the tube through about 90 °), but curve gently within the central bore 34 of the plug 32, to decrease the potential for occlusion of the shunt 10 by kinking the tube 12 or allowing trapping of fibrin clots within this turn of the tube 12. The frontal sinus plug 32 should be compressible to allow the lower flange 40, having a diameter slightly larger than the trephined hole 25, to be introduced into the frontal sinus (preventing unintentional egression of the shunt 10), and providing pressure against the bony walls of the trephined hole 25 to stop hemorrhage from the bone 18 and to stop fibrin and blood from collecting around the valve device 26.

Without being limiting, in one embodiment of the shunt designed for dogs, the center portion 36 has a diameter of about 0.25-1.5 mm, which is approximately equal to the bore dimensions of the trephined hole 25, and approximately 0.1 mm shorter than the thickness of the bone 18 (1 - 2.5 mm), to create a tight sealing fit to prevent haemorrhage from the bone 18 that may drain onto the valve device 26. The external diameter of the flanges 38, 40 are about 0.1 - 0.6 mm greater than the outside diameter of the tube 12, and at least twice the diameter of the trephined hole 25 to prevent complete ingress into the frontal sinus 16.

As indicated above, the shunt of the present invention, and its parts, are formed from biocompatible materials, that is materials which are biologically non-reactive and non-toxic to the patient. Examples are silicone (sialastic tubing), glass, medical grade plastic and some metals.

Second and third embodiments of the shunt 10 are shown in Figures 6 - 10. In Figure 6, the valve device 26 is shown to include a drainage reservoir 42 housing a valve element (not shown). In Figure 7, the drainage reservoir 42 is shown to also function as the sealing device 24 in the frontal bone 18. A variety of check valve types may be incorporated in these embodiments, such as the nipple plug type valve shown in Figures 7 - 10, or a butterfly valve (not shown). The reservoir 42 is shown in the figures to be formed from an apertured upper plate 44, a closed bottom plate 46, connected together by a side wall 48 which includes perforations such as longitudinal slits 50 which allow fluid to drain from the reservoir 42.. In Figure 7, the reservoir 42 is shown to include a widened sealing flange 52, to seal and anchor

against the frontal sinus bone 18. The nipple plug type valve components are best shown in Figure 10, to include an upper orifice plate 54 and a lower nipple plug 56 operative to seal in the orifice plate 54. The plate 54 and plug 56 are joined together in a normally closed position (shown in Figure 8), by a spring member 58, having a tension such that the valve is fluid openable under predetermined pressures associated with glaucoma to allow fluid to flow through the orifice plate 54 and out the perforations 50. When implanted, once the pressure diminishes the nipped plug 56 will reseal against the orifice plate 54.

Method of Treatment of Glaucoma - Surgical Implantation and Testing

Surgical implantation of the shunt 10 in accordance with the present invention is described below, following aseptic preparation of the surgical field including the eye and skin of the patient and positioning the patient under an operating microscope. Over the ipsilateral frontal bone, the skin, subcutaneous tissues, and muscle over the zygomatic process of the frontal bone are incised. The incision should be long enough to expose the frontal bone over the frontal sinus (typically approx 1" long and oriented rostrocaudally. The location of the frontal sinus 16 can be confirmed by tapping the frontal bone of the zygomatic process with a solid object (such as a surgical instrument) to confirm a hollow sound.

A drilling device (such as a Jacob's chuck and Steinmann's pin- not shown), sized appropriately for the patient, is employed to make the hole 25 in the bone 18 over the frontal sinus 16, into the frontal sinus 16 from the exterior. The size of the hole 25 will vary with patient and species, and is matched to the size of the sealing device 24. The sinus is visualized as a white cavity.

Patency of the shunt 10 is confirmed by (i) cannulating the shunt (anterior chamber end 22) with a aqueous-fluid-filled syringe and needle (typically 27-30 ga.) assembly - not shown; (ii) flushing the aqueous fluid (e.g. sterile balanced salt solution) through the shunt 10 under pressure from the syringe; and (iii) visualizing fluid passing through the valve device 26.

The frontal sinus end 20 of the shunt 10 is placed within the trephined hole 25 of the sinus and can be held in place by slight compression of the sealing device 24 and by the upper and lower flanges 38, 40.

An eyelid speculum, not shown, is then placed ipsilaterally on the eyelids to expose the conjunctival surface. A conjunctival incision is made from the limbus (junction of cornea, sclera, and conjunctiva) to the fornix (reflexion of the conjunctiva under the eyelid) and

extended through to the episclera.

An instrument such as pair of small forceps, not shown, is used to bluntly dissect a tunnel from the conjunctival incision to the frontal sinus incision (typically over the dorsal rim of the orbit to the original surgical dissection exposing the frontal sinus). When the tip of such instrument can be visualized it can be used to grasp the free end (anterior chamber end 22) of the shunt. The shunt 10 is then drawn back through the tunnel through the conjunctival incision. The shunt 10 is layed across the surface of the cornea and the length of the shunt is trimmed so as to adjust its length such that it rests approximately 1/4 of the vertical length of the anterior chamber 14. The anterior chamber end 22 of the shunt is trimmed obliquely at 45 to 60 degrees with the bevel opening anteriorly.

A cutting device (e.g., 20 gauge disposable stiletto blade, not shown) is used to enter the anterior chamber 14 at the limbus. The angle at which the blade enters the anterior chamber should be approximately 20° (the shunt 10 should enter the anterior chamber 14 at 10 - 25° anterior to the limbal plane to ensure that the shunt is positioned equal distance between the iris and the cornea to avoid contact between the shunt and the iris, crystal lens, or corneal endothelium).

Small forceps (e.g. tying forceps) are used to grasp the anterior chamber end 22 of the shunt near the bevelled end, and the shunt 10 is inserted into the anterior chamber 14. The shunt 10 is anchored to the sclera with, for example, nonabsorbable (monofilament) more than one (usually to or maximally (practically) three) sutures in a simple interrupted pattern.

The Tenon's capsule and conjunctiva are closed with, for example, simple interrupted sutures of small (7-0 to 10-0) monofilament absorbable sutures. The frontal sinus end 20 of the shunt is withdrawn from the frontal sinus 16 and monitored for flow of aqueous humor through the valve device 26. When fluid flow through the valve device 26 is confirmed, such flow is adjusted at the valve device 26. In the case of a slit valve, the flow is adjusted with at least one ligature device 30 around or adjacent the slit 28 to maintain a desired intraocular pressure, which can be measured at the corneal surface with an applanation tonometer in the O.R. (normal for dog approximately 18 mm Hg). The valve device 26 is adjusted to open above this predetermined and known fluid pressure associated with glaucoma. The predetermined fluid pressure associated with glaucoma is known for other species, and the valve device can be adjusted accordingly for other species.

The frontal sinus end 20 of the shunt 10 is then replaced into the frontal sinus 16.

Subcutaneous tissues are closed with, for example, small (3-0 to 6-0) monofilament absorbable sutures in a simple continuous pattern. The skin is subsequently closed with, for example, small (3-0 to 5-0) monofilament nonabsorbable suture in a simple interrupted pattern.

It is common with all intraocular shunts to become fibrin coated or occluded with fibrin shortly after surgery (within the first week post-surgery). The shunt 10 of this invention can be flushed through the valve device 26 by incising the skin, removing the frontal sinus end 20, and back flushing an antifibrinolytic compound (e.g. tissue plasminogen activator (TPA)) retrograde through the shunt. Subsequent flushing of the shunt 10 with TPA or saline in the event of occlusion of the shunt is accomplished by exposing the frontal sinus end 20 of the shunt 10, removing it from the sinus 16, and flushing the shunt retrograde. When flow is observed and the desired intraocular pressure is attained by adjusting the valve device 26, e.g. adjusting the ligature devices 30, the frontal sinus end 20 of the shunt is then replaced, and the surgical site closed as described above.

In the event that the intraocular pressure is observed to be routinely less than the desired intraocular pressure, the frontal sinus end 20 of the shunt 10 can be exposed and ligatures placed at various intervals along the slit 28 to attain the desired intraocular pressure.

Example

A shunt of the present invention was designed for and successfully implanted into four dogs having glaucoma. The details of the implanted shunt were as follows:

Tube and Slit Valve

Inner Diameter 0.02" (0.5 mm)

Outer diameter 0.037" (0.94 mm)

Length of Tube (rough cut to be 100 mm) then tailored to each eye in the operating room so that it extended approximately 1/3 away across the anterior chamber of the eye.

Slit – 1mm length

Ligatures – 4 – to maintain predetermined fluid pressure, adjusted in the operating room

Hole in the Frontal sinus bone (diameter) – (2 mm)

Plug (sealing device)

Central Portion (that traversed the width of the bone) – (1.5 mm)

Lower flange – 2.5 mm

Upper Flange – 5 mm

Length of Plug (Central Portion – traversing the bone) – 3 mm

These patients did not experience frontal sinus, subcutaneous, conjunctival or intraocular infections; fibrosis, haemorrhage, or other untoward complications. Each of the four patients was reoperated on within days of the first surgery to establish and verify shunt patency and operation and to demonstrate readjustment of the valves and retrograde flushing. Each patient was and is continually to be monitored for visual function and untoward side effects. All anti-glaucoma medications have been discontinued. Regular re-examination with tonometry, visual function testing, biomicroscopy and indirect ophthalmoscopy has demonstrated maintenance of vision and desired intraocular pressures for period of up to 2 years post initial surgery.

Advantages

Generally, eyes inflicted with glaucoma build up protein in the aqueous humor. Prior art implanted drainage devices often become blocked with the protein, inhibiting fluid drainage from the eye. To correct this problem with prior art glaucoma treatment devices, an additional invasive surgery is needed to clean, remove, or replace the implant. The method and shunt of the present invention allows the correction to be made by a simple skin incision above the frontal sinus. The sealing device 24 and anterior chamber end 22 of the tube 12 are removed from the frontal sinus 16, flushed with sterile fluid, and reinserted. Further cleanings are not normally required. The fibrous tissue that collects around the shunt once implanted forms a tunnel from the sinus incision to the anterior chamber 14. If the shunt 10 needs to be replaced, the original can be removed through the sinus incision and a new device inserted through the tunnel created by the fibrous tissue. An extensive surgery is not required.

All publications mentioned in this specification are indicative of the level of skill in the art to which this invention pertains. To the extent they are consistent herewith, all publications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference. No admission is made that any cited reference constitutes prior art.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity and understanding it will be understood that certain changes and modifications may be made without departing from the scope or spirit of

the invention as defined by the following claims.

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U.S. Patents 5,454,796 and Des. 356,867 to Krupin (Hood Laboratories).

We claim:

1. A shunt for implantation between the anterior chamber of the eye and the epithelial-lined space through the frontal sinus bone of a patient for the treatment of glaucoma, comprising:

a tube having a length sufficient to span the distance between the anterior chamber of the eye and the epithelial-lined space of the patient, the tube having an open anterior chamber end and a closed epithelial-lined space end;

a seal device associated with the tube between the anterior chamber and epithelial-lined space ends, for sealing a hole in the frontal sinus bone, and for anchoring the tube against movement from the frontal sinus bone; and

a fluid pressure openable valve in the tube, located at or near the epithelial-lined space sinus end, allowing for controlled flow of aqueous humor through the tube when implanted.

2. The shunt of claim 1, wherein the epithelial-lined space is the frontal sinus, and the closed end of the tube is thus the frontal sinus end.

3. The shunt of claim 2, wherein the pressure openable valve is a longitudinal slit in the tube, and one or more ligature devices around the tube overlying or adjacent the slit such that adjustment of the one or more ligature devices adjusts fluid flow through the valve.

4. The shunt of claim 2, wherein the shunt further comprises a reservoir located at the closed frontal sinus end of the tube, said reservoir having a side wall forming one or more apertures through which fluid can flow from the tube, and wherein the pressure openable valve is located in the reservoir.

5. The shunt of claim 4, wherein the pressure openable valve comprises a pair of spaced apart discs connected together by a spring member, the disc facing the anterior chamber end being apertured to allow the valve to open with a predetermined fluid flow pressure from the anterior chamber end.

6. The shunt of claim 5, wherein the pressure openable valve is a tapered nipple type valve.

7. The shunt of claim 5, wherein the pressure openable valve is a butterfly type valve.

8. The shunt of any preceding claim, wherein the seal device comprises a widened portion of the tube, or a pliable spool-shaped plug fixed to the tube and through which the tube is threaded, said plug having upper and lower pliable flanges which seal on either side of the hole in the frontal sinus bone and which prevent movement of the plug relative to the

frontal sinus bone, the upper flange being anterior chamber facing and being sufficiently pliable to be slid through the hole in the frontal sinus bone.

9. The shunt of any preceding claim, wherein the sealing device or plug bends the tube through an angle sufficient to prevent kinking of the tube as it is implanted between the anterior chamber and the frontal sinus.

10. The shunt of claim 8, wherein the sealing device or plug bend the tube through an angle of between 80 and 100°.

11. A method of treating glaucoma in a patient, comprising:

forming a hole from the exterior into the epithelial-lined space of the patient;
surgically implanting through the hole, between the anterior chamber and the epithelial-lined space, a shunt having a fluid pressure openable valve; and
draining aqueous humor from the anterior chamber through the shunt to the epithelial-lined space.

12. The method of claim 11, wherein the epithelial-lined space is the frontal sinus, and the hole is formed in the frontal sinus bone.

13. The method of claim 12, wherein the shunt includes a tube having an open anterior chamber end and a closed frontal sinus end, and wherein the valve is located at the frontal sinus end, allowing for controlled flow of aqueous humor through the tube when implanted..

14. The method of claim 13, wherein the pressure openable valve is a longitudinal slit in the tube, and one or more ligature devices around the tube overlying or adjacent the slit such that adjustment of the one or more ligature devices adjusts fluid flow through the valve.

15. The method of claim 13, wherein the shunt further comprises a reservoir located at the closed frontal sinus end of the tube, said reservoir having a side wall forming one or more apertures through which fluid can flow from the tube, and wherein the pressure openable valve is located in the reservoir.

16. The method of claim 15, wherein the pressure openable valve comprises a pair of spaced apart discs connected together by a spring member, the disc facing the anterior chamber end being apertured to allow the valve to open with a predetermined fluid flow pressure associated with glaucoma from the anterior chamber end.

17. The method of claim 16, wherein the pressure openable valve is a tapered nipple type valve.

18. The method of claim 16, wherein the pressure openable valve is a butterfly type valve.

19. The method of any preceding claim, wherein the shunt further comprises a seal device between the anterior chamber and frontal sinus ends of the tube, for sealing the hole in the frontal sinus bone, through which the tube is inserted, and for anchoring the tube against movement from the frontal sinus bone.

20. The method of claim 19, wherein said seal device comprises a widened portion of the tube, or a pliable spool shaped plug fixed to the tube and through which the tube is threaded, said plug having upper and lower pliable flanges which seal on either side of the hole in the frontal sinus bone and which prevent movement of the plug relative to the frontal sinus bone, the upper flange being anterior chamber facing and being sufficiently pliable to be slid through the hole in the frontal sinus bone.

21. The method of any preceding claim, wherein the sealing device or plug bends the tube through an angle sufficient to prevent kinking of the tube as it is implanted between the anterior chamber and the frontal sinus.

19. The shunt of claim 21, wherein the sealing device or plug bend the tube through an angle of between 80 and 100°.

FIG. 1

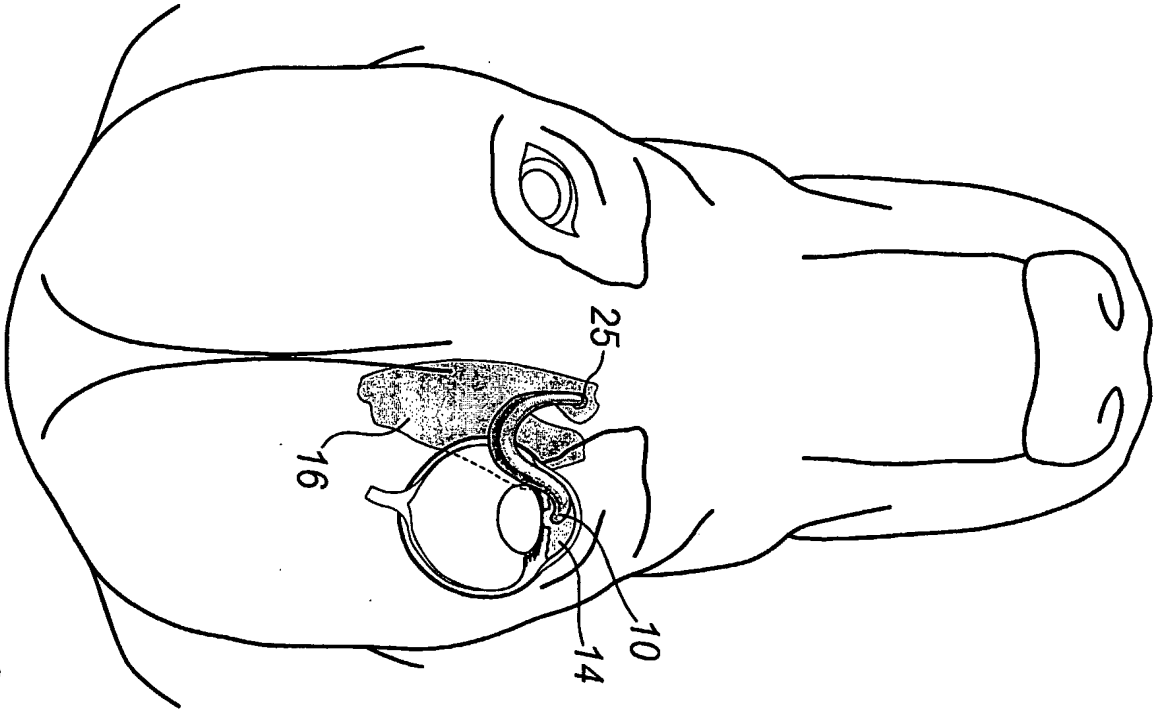
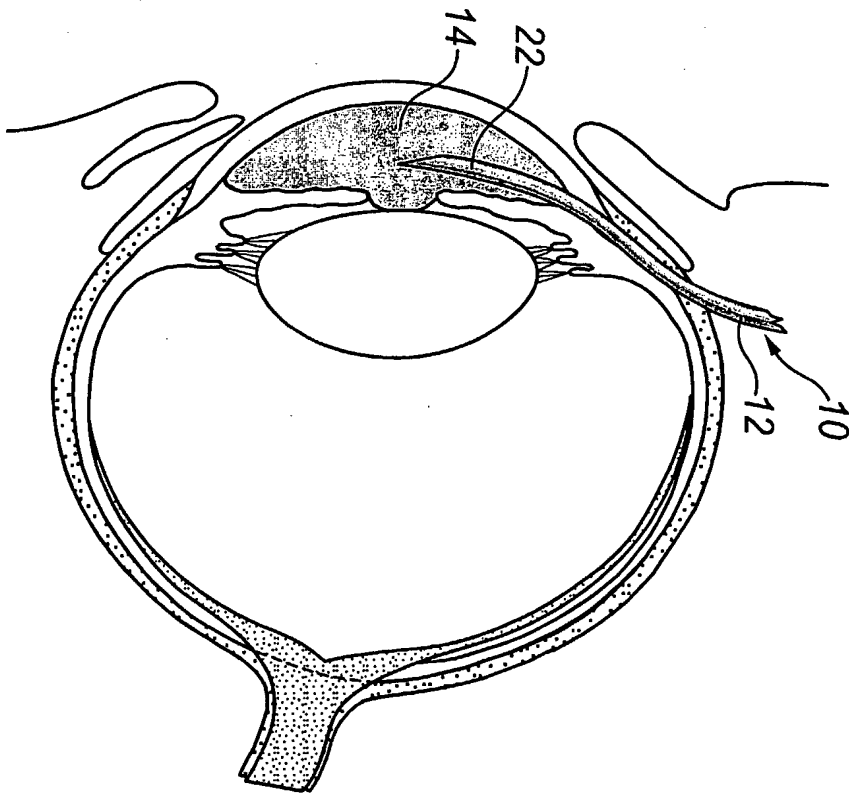


FIG. 2



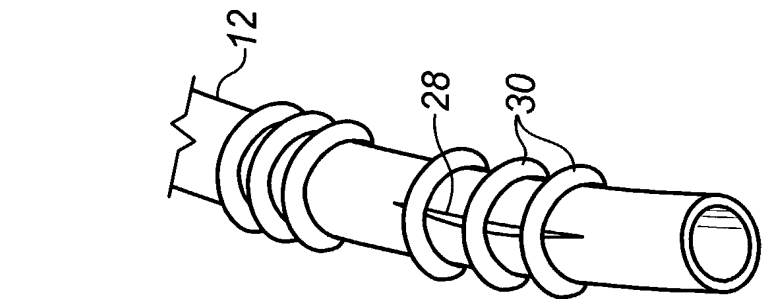


FIG. 5

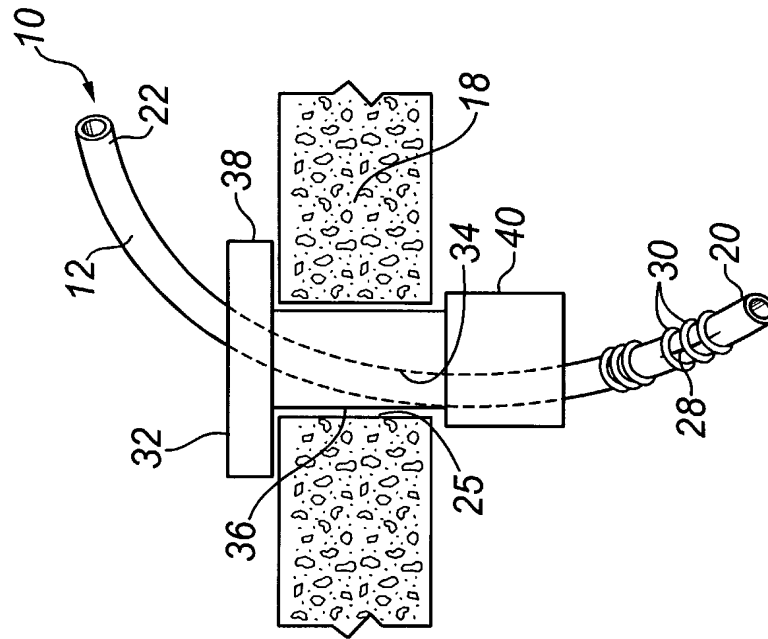


FIG. 4

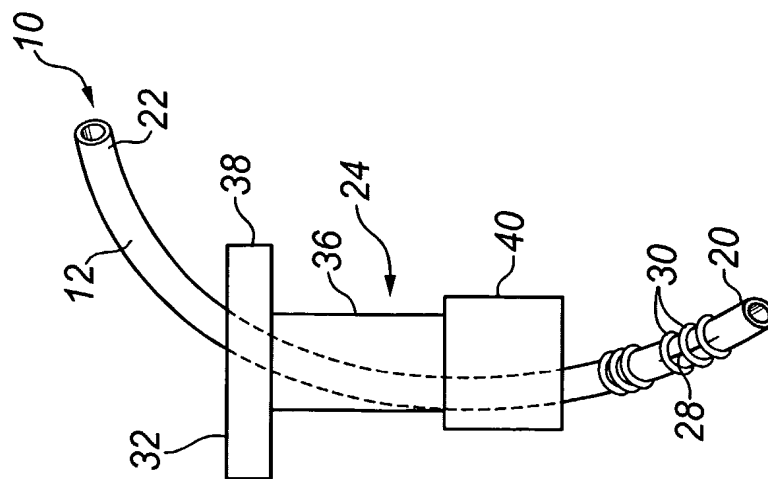


FIG. 3

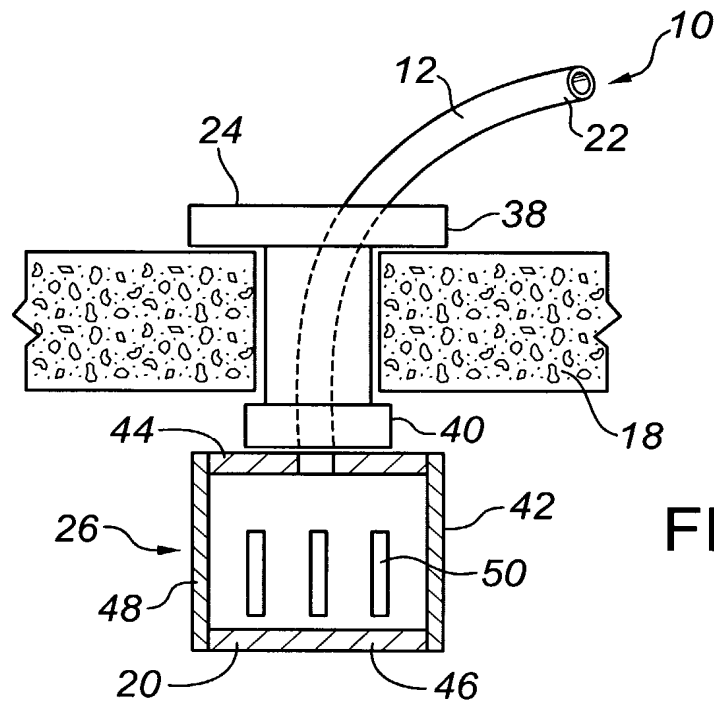


FIG. 6

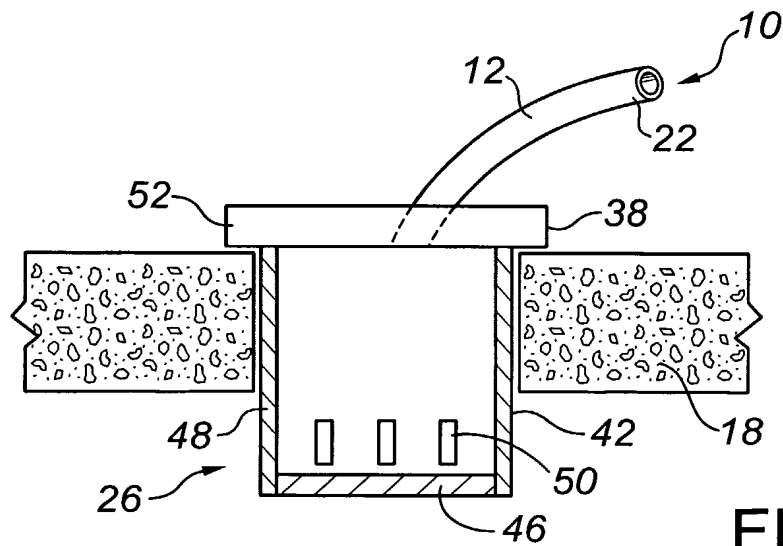
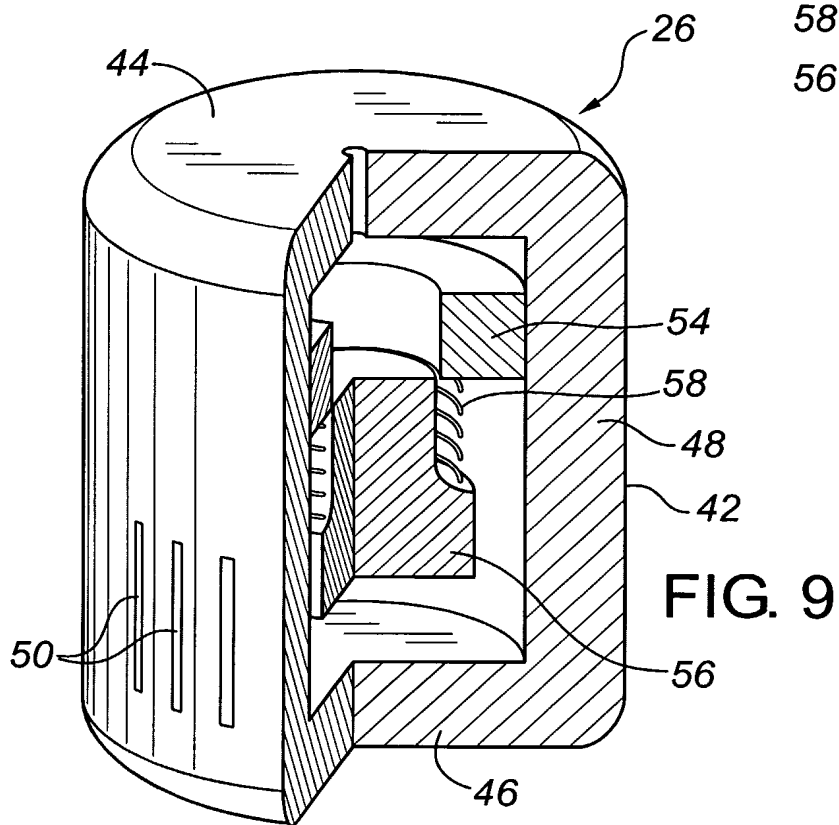
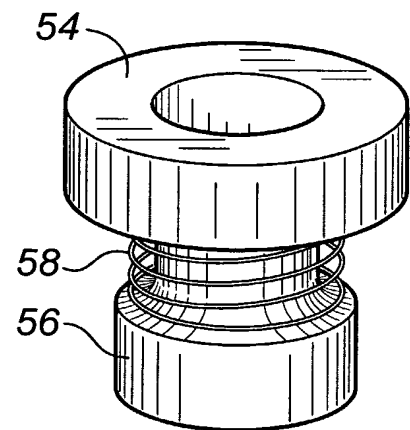
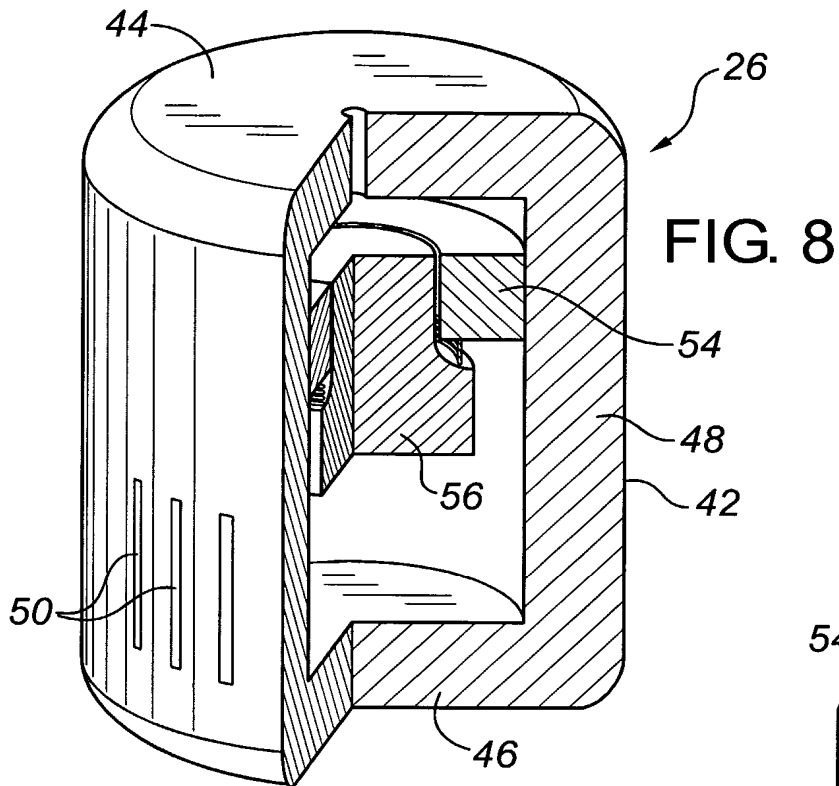


FIG. 7



INTERNATIONAL SEARCH REPORT

International Application No.

PCT/CA 03/00774

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F9/007 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

BIOSIS, EPO-Internal, WPI Data, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>CULLEN CHERYL L ET AL: "Anterior chamber to frontal sinus shunt for the diversion of aqueous humor: A pilot study in four normal dogs."</p> <p>VETERINARY OPHTHALMOLOGY, 'Online! vol. 1, no. 1, 1998, pages 31-39, XP002256453</p> <p>ISSN: 1463-5216</p> <p>Retrieved from the Internet: <URL:http://www.blackwell-synergy.com/links/doi/10.1046/j.1463-5224.1998.00013.x/full/> 'retrieved on 2003-10-02!</p> <p>cited in the application</p> <p>Pages 31-39 as cited correspond to pages 1-13 of the article as retrieved from the internet</p> <p>Sections "Introduction" and "Materials and Methods"</p> <p style="text-align: center;">---</p> <p style="text-align: center;">-/--</p>	1-4

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

° Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *P* document published prior to the international filing date but later than the priority date claimed

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- * & * document member of the same patent family

Date of the actual completion of the international search

22 October 2003

Date of mailing of the international search report

12/11/2003

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Rick, K

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 03/00774

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 338 291 A (SPECKMAN LORI C ET AL) 16 August 1994 (1994-08-16) column 2, line 26 -column 3, line 36 column 4, line 57 -column 5, line 31 column 5, line 59 -column 6, line 18; figures 1-4 ----	1-4
Y	US 4 037 604 A (NEWKIRK JOHN B) 26 July 1977 (1977-07-26) column 1, line 26 - line 62 column 2, line 6 -column 3, line 46; claim 1; figures 1-3 ----	1,2,4
A	US 4 554 918 A (WHITE THOMAS C) 26 November 1985 (1985-11-26) column 2, line 3 -column 4, line 68 column 6, line 17 - line 24; figures 2,5,8 ----	1-10
A	US 4 604 087 A (JOSEPH NEIL H) 5 August 1986 (1986-08-05) column 3, line 43 -column 5, line 7 column 5, line 55 -column 6, line 22; figures 1,3-5,7 ----	1-10
A	EP 0 228 185 A (WHITE THOMAS C) 8 July 1987 (1987-07-08) column 7, line 29 -column 9, line 35; figures 1,6,12 -----	1-10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 03/00774

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 11-22
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA 03/00774

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